

XIV. STUDY PROCEDURES IN THE EVENT OF AN INFANT DEATH

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XIV. STUDY PROCEDURES IN THE EVENT OF AN INFANT DEATH

A. Notification of NICHD and DCAC of Death

Once a site is informed of a study infant's death, the site should immediately notify CHIME's Program Director at NICHD of the death, complete an **Incident Report Form (J1)** and fax it to the DCAC (617-638-5066).

B. Documentation of Death

1. Complete an Incident Report (J1) form

a) Write in the name(s) of all individuals involved in the incident, (Q#1) the date and time of the incident, (Q#2) whether the incident involved equipment, use of a non-study monitor, potential or personal injury of an infant, caregiver, study personnel, vendor or other individual, (Q#3) the location where the incident occurred and (Q#4) the type of the equipment (if any) involved.

b) Describe the incident in clear, concise terms (what happened, who was involved, where did it occur, when did it happen and how) (Q#5).

c) Describe the investigation of the incident at the site both planned and completed (Q#6). Include details of the investigation such as the type of data obtained, any testing that was done, interviews or home visits made and results.

d) Describe all corrective action taken at the site both planned and completed (Q#7). Include instructions given to caregivers, any treatment of injury or equipment replacement.

e) A CHIME Investigator **MUST** sign and date page 2 of the Incident Report form **BEFORE** faxing it to the DCAC.

f) An Incident Report Form must be completed and **FAXED** to the DCAC (617-638-5066) **within 48 hours of the site being notified of the incident.**

2. Processing of Incident Reports at the DCAC

For each Incident Report form received by the DCAC, a four digit incident tracking number is assigned. The names of all individuals involved in the incident are removed from the report before copies are faxed to the Project Officer at NICHD (Dr. Marian Willinger) and the CTOC (Dr. Michael Neuman). The death will require further review by the CHIME Incident Review Committee (Drs. Lister, Corwin, Hunt, Keens). Copies of the Incident Report will be faxed to committee members for discussion and resolution.

The DCAC tracks the status of each Incident Report using an Incident Follow-up Form (J2). An Incident Report remains 'active' until a final action or resolution has been made, at which time the Incident Report (J1) and the Follow-up Form (J2) are completed and filed. The CTOC and CHIME Engineers assist in evaluating and resolving any Incident Reports which involve technical issues or equipment

function.

3. Notifying the DSMB

The Data Safety Monitoring Board is informed of all incidents by Theodore Colton, Sc.D., from the DCAC, either by periodic reports or at yearly meetings.

C. Review of CHIME Information

All clinical sites should have in place standard procedures for clinical care of subjects in the CHIME study. These procedures should include the review performed on physiologic data and the response to any abnormalities identified.

In the event of a death, the site should perform a review to verify that all information that should have been evaluated as part of the standard procedures was examined and, when appropriate, acted upon. If this review uncovers data that may contribute to the interpretation of the cause of death, the information should be forwarded to the medical examiner.

Following a death, sites should not review data or perform analyses that are not part of their standard clinical procedures. Such analyses will be performed as part of the primary hypothesis testing for this project. Early analysis of data from subjects who experience specific outcomes (e.g. death) will be performed only as directed by the DSMB.

D. Death Scene Investigation

Any infant who dies suddenly and unexpectedly during the first year of life, whether or not he/she was using a home monitor at the time of death, will undergo a thorough death scene investigation and post-mortem examination. Each Clinical Site will make arrangements with the local Coroner/Medical Examiner's office for death scene investigations and post-mortem examinations on study infants to be performed in a standardized manner.

1. A death scene investigation will be performed to assist in determination of the cause of death.
2. Death scene investigations should be performed by trained and experienced coroner's investigators. A standardized protocol, modeled after the California mandated uniform Unexpected Infant Death Scene Investigation (1989 SB 1069) modified by the Maternal-Child Branch of the *National Institute of Child Health and Human Development*, will be used.
3. In many cases, death occurs at home, but the infant is rushed to a nearby Emergency Medical Services facility. In such cases, it is often difficult find parents or caregivers and return to the death scene for an investigation.

E. Post-Mortem Examination

1. A post-mortem examination will be performed to assist in determination of the cause of death. In many states where Clinical Sites are located, a post-mortem examination is mandated by state law for infants in whom the cause of death may be SIDS.
2. Post-mortem examinations should be performed by qualified pathologists, preferably with experience and expertise in pediatric pathology and SIDS. A standardized protocol, modeled after the California mandated uniform Unexpected Infant Death Autopsy Protocol (1989 SB 1069), modified by the Maternal-Child Branch of the *National Institute of Child Health and Human Development*, will be used.

F. Study Pathologists

One or more pathologists from each Clinical Site will comprise a committee to define the specific manner in which the above investigations will be performed in a uniform manner at each site. The Primary Investigator should contact the chairman, Henry Krous, if a study infant dies at their site, to insure that the investigation is conducted properly.

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POSITION STATEMENT

INFANTS DYING SUDDENLY AND UNEXPECTEDLY AFTER SIDS IN A PREVIOUS SIBLING

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Sudden Infant death syndrome (SIDS) is the most common cause of postneonatal infant mortality in the United States. It has an incidence of approximately 1 in 1000 live births. It has been reported that the recurrence risk of SIDS in a subsequent sibling is increased; however, some are of the opinion that if the first infant's death was a "classical" SIDS, then the recurrence risk may be no higher than that in the general postneonatal infant population. However, if a third infant dies suddenly and unexpectedly in the same family, then suspicion of homicide is enhanced although one, of course, must keep in mind the possibility of underlying previously unrecognized metabolic disorders or hazardous sleeping environments. Further, data from Western Europe, Australia and New Zealand have shown that the recent reduction in the SIDS incidence has reduced the winter incidence, flattened the peak age curve, and increased the frequency of 'non-classical' SIDS cases. In these latter cases, home environments may be suboptimal, the sleep site is potentially hazardous, and pathologic findings are often more difficult to interpret. Therefore, there appears to be an emerging tendency for medical examiners and coroners who made a diagnosis of SIDS in a first infant to a sibship to diagnosis siblings for whom causes for death are not found as "undetermined".

To avoid potential misclassification of true SIDS as "undetermined", the Pathology Committee of the CHIME Study will meet on a regular basis to review the records and microscopic slides of cases coming to autopsy in order to establish study diagnoses, to review the adequacy of materials to reach those diagnoses, and to exchange information and educate one another about important findings relevant to establishing the cause of death of these infants.